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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/527,725 | 03/14/2005 | Robert W. Shaw | 218601.00007 (TXTECH-0001) | 1002 |
| 25555 | 7590 | 03/05/2007 | EXAMINER | |
| JACKSON WALKER LLP 901 MAIN STREET SUITE 6000 DALLAS, TX 75202-3797 | | | KIM, YOUNG J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1637 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 31 DAYS | 03/05/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/527,725

Applicant(s)

SHAW ET AL.

Examiner

Young J. Kim

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-36, drawn to a method of identifying a nucleic acid ligand to a lactamase and a first product produced by said method. If this Group is elected, a further species requirement will be necessary as instructed below.

Group II, claim(s) 37-41, drawn to a composition comprising a nucleic acid ligand with SEQ ID Number 4.

Group III, claim(s) 42-46, drawn to a composition comprising a nucleic acid ligand with SEQ ID Number 5.

Group IV, claim(s) 47, drawn to a composition comprising a nucleic acid ligand with SEQ ID Number 6.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

With regard to the unity of invention between Group I (herein, "A") and Groups II-IV (herein, "B"), there lacks a special technical feature which is shared between A and B. The special technical feature defining its contribution over prior art in B is the actual SEQ ID Numbers, which are not shared by any of Groups in A, thereby lacking a special technical feature which may provide for a unity of invention.

In addition, there lacks a unity of invention among Groups II-IV, because the nucleic acid ligand in each of the Groups comprise different sequence (thus structurally unrelated).

Further, 37 CFR 1.475 which governs Lack of Unity practice in International and National Stage Application recites that an international or a national application containing claims to different categories of invention will be considered to have unity of invention *if the claims are drawn to only one of the following combination of categories:*

- 1) a product and a process specially adapted for the manufacture of said product; or
- 2) a product and process of use of said product; or
- 3) a product and a process specially adapted for the manufacture of said product; and a use of said product; or
- 4) a process and an apparatus or means specifically designed for carrying out the said process; or
- 5) a product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Instant application contains three different products (*i.e.*, composition) comprising three different nucleic acid ligands (as denoted by their different SEQ ID Numbers). 37 CFR 1.475 states that if an application contains claims to “more or less than one of the combination of categories of invention set forth in paragraph (recited above), unity of invention might not be present. Since the first method and the first composition, categorized by a single category of invention, have already been grouped together, the additional compositions would lack unity of invention as being drawn to an additional category. Additionally, the three compositions would lack unity of invention as the special technical feature critical to the invention, that is the SEQ ID Number, is not shared between the two compositions, as their sequences are clearly different.

Additional Species Requirement

Group I contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

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I – method of assaying for a nucleic acid candidate:

- a) Employing salt concentrations for stringency (claims 1-11); or
- b) Employing temperature for stringency (claims 12-22);

II – type of lactamase:

- a) *B. cereus* 5/B/6 metallo- β -lactamase (claims 5, 16, 26, and 33); or
- b) *B. cereus* 569/H/9 metallo- β -lactamase (claims 6, 17, 26, and 34)

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: claims 1-4, 7-15, 18-25, 28-32, 35, and 36 are generic with respect to the species requirement of II. No claims are generic with respect to the species requirement of I.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

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With regard to the species requirement of I, the two methods employ technical features which are not shared, that is, one species of method employs salt concentration while the other species of method employs temperature, thus not linked by a special technical feature.

With regard to the species requirement of II, the two species assay for two different species of lactamase, and hence, do not share a special technical feature.

A telephone call was not made to request an oral election to the above restriction requirement due to the complex nature of the requirement (MPEP § 812.01).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m (M-W and F). The

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Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.


Young J. Kim

Primary Examiner

Art Unit 1637

3/2/2007

**YOUNG J. KIM
PRIMARY EXAMINER**

YJK